UPDATE: FDA Discourages Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy

In May 2014, Coverys published an Instant Email that was based on the U.S. Food and Drug Administration’s (FDA’s) Safety Communication issued in April 2014 regarding the use of laparoscopic uterine power morcellation in hysterectomy and myomectomy.

The FDA issued an updated Safety Communication on November 24, 2014, strengthening its warnings against the use of the controversial uterine surgical technique. In the updated communication, “the FDA is warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids.”

The updated information from the FDA includes new contraindications, a new boxed warning, and a recommendation to carefully consider all available treatment options and thoroughly discuss the benefits and risks of all treatments with patients.

In an Immediately in Effect (IIE) guidance, “the FDA is asking manufacturers of new and existing laparoscopic power morcellators to include two contraindications and a boxed warning in their product labeling.” Asking manufacturers to place “boxed” warnings on the devices is the strongest type of labeling a product can have while still remaining on the market.

The FDA’s November 24, 2014 News Release on this topic included the following statements:
"The FDA’s primary concern is the safety and well-being of patients and taking these steps will help the agency’s safety recommendations to be implemented as quickly as possible,” said William Maisel, M.D., M.P.H., deputy director for science and chief scientist at the FDA’s Center for Devices and Radiological Health. "Updating the device label with a boxed warning and contraindications will provide clinicians and patients with critical information about the risk of spreading cancerous tissue when these procedures are performed."

The boxed warning informs healthcare providers and patients as follows:
The FDA warns that uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

The two contraindications are stated by the FDA as follows:
1. Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or mini-laparotomy incision. (Note: These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)

2. Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

The two contraindications help to clarify the narrow population of patients in which laparoscopic power morcellation may be an appropriate therapeutic option. For example, some younger women who are interested in maintaining their ability to have children or wish to keep their uterus intact after being informed of the risks may be candidates for this procedure.

Finally, the FDA’s News Release also contained the following statements:
"The FDA strongly encourages doctors to inform their patients of the risk of spreading unsuspected cancer from the use of these devices in fibroid surgery and discuss the benefits and risks associated with all treatment options,” said Dr. Maisel.
There are other surgical treatment options available for women with symptomatic uterine fibroids, such as traditional surgical hysterectomy (performed either vaginally or abdominally) and myomectomy, laparoscopic hysterectomy and myomectomy without morcellation, and laparotomy using a smaller incision (minilaparotomy). …

In addition to the updated safety communication and IIE guidance, the FDA is considering other ways to further help reduce the risk of unsuspected cancer spread by laparoscopic power morcellation, such as encouraging innovative ways to better detect uterine cancer and contain potentially cancerous tissue.

The agency will continue to review adverse event reports, peer-reviewed scientific literature and information from patients, health care professionals, gynecologic and surgical professional societies and medical device manufacturers and may take further action in the future, if necessary.9

Coverys will continue to provide updates as they become available. For more information, please refer to the FDA’s updated Safety Communication on this topic, available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm.

References

2. Ibid.
3. Ibid.
7. Ibid.
9. Ibid.

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